

## REMARKS

### Rejection of Claims 1 and 3 under 35 U.S.C. § 102(b)

As indicated above, claim 1 has been amended to more clearly point out the claimed invention. Claim 3 has been cancelled without prejudice.

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brine (U.S. Patent No. 5,075,115). As indicated above claim 3 has been cancelled. In the prior Office Action the Examiner contended that Brine teaches (i) polymers of lactic acid with a molecular weight of 2500-4500 and (ii) terpolymers with other hydroxycarboxylic acids such as glycolic acid, caprolactone and valerolactone. Based upon these contentions the Examiner alleges that original claim 1 is anticipated by Brine based upon the argument that the claimed properties recited in the rejected claim must be possessed by the compounds taught by Brine since they are the same composition.

Applicants respectfully point out that amended claim 1 (here after referred to as claim 1) recites that the matrix comprises, for example, a thermoplastic terpolymer selected from the group consisting of poly(lactide/glycolide/caprolactone) and poly(lactide/glycolide/valerolactone).

As indicated above, the Examiner contends that Brine teaches polymers of lactic acid with a molecular weight of 2500-4500 and Terpolymers with hydroxyl carboxylic acids. However, Brine does not teach the lactide-containing terpolymers formed from a mixture consisting of hydroxycarboxylic acid monomers as recited by claim 1. Therefore, the rejection of claim 1 based on Brine is improper.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The Examiner contends that Brine teaches terpolymers of lactic acid with other hydroxycarboxylic acids. Contrary to the Examiner's contention, Brine makes no mention whatsoever of terpolymers. Brine teaches poly(lactic acid) mixed with copolymers/homopolymers of other hydroxycarboxylic acids. For example, the specification of Brine states that "the present invention is a process for polymerizing lactic acid to poly(lactic acid) . . . the present invention is intended to include the product made by the process as well as copolymers and mixtures of polymers of glycolic acid, valerolactone, caprolactone, decalactone, hydroxybutyric acid, hydroxyvaleric acid and dioxanone . . . " (see column 3, lines 5-32). Furthermore, Examples 1 and 2 teach a blend of

a poly(DL-lactic acid) polymer and a polycaprolactone polymer and Table 1, entitled "Polymer Overview" teaches only poly(L-lactic acid), poly(DL-lactic acid), and polycaprolactone polymers.

Hawley's Chemical Dictionary, 13<sup>th</sup> edition, defines terpolymer as "a polymer made from three monomers. Brine teaches polymers made from poly(lactic acid) and other hydroxycarboxylic acids, and, poly(lactic acid) is by definition a polymer, not a monomer. Therefore, Brine does not teach lactide-containing terpolymers (i.e., a polymer formed from a mixture of three monomers, one of which is a lactic acid monomer). Rather, Brine teaches poly(lactic acid) mixed with homopolymers/copolymers of other hydroxycarboxylic acids. A recited element of the invention of claim 1 is a lactide-containing terpolymer formed from a mixture having hydroxycarboxylic acid monomers. Accordingly, Brine is not teaching the same composition and therefore it cannot be said to possess the same properties recited in claim 1. As such Brine can not be properly relied upon to support a rejection of claim 1 under 35 U.S.C. § 102.

Furthermore, claim 1 recites that the claimed terpolymers exhibit an "adhesive strength of about 600 to about 150,000 Pa" so that the matrix is tissue adherent. Brine discloses the use of poly(lactic acid) in dosage forms for the controlled release of pharmaceutically active compounds. Brine is silent on the characteristics of his disclosed poly(lactic acid) compositions. Notably, Applicants' sticky polymers would complicate (gum up the machine) the tableting of, for example, tableting compositions used to prepare tableted controlled release dosage forms. An "adhesive strength of about 600 to about 150,000 Pa" is a recited element of the invention of claim 1 and Brine does not teach this element. Further, the polymer compositions taught by Brine necessarily (to be used as taught by Brine) have properties different than the polymers of the present invention. Therefore, Brine cannot be said to anticipate claim 1.

In sum, Brine (U.S. Patent No. 5,075,115) does not describe the terpolymers recited in claim 1, accordingly Brine can not be the same compositions recited in claim 1. In addition Brine does not teach a polymer having adhesive strength of about 600 to about 150,000 Pa, and such a polymer would not work in the technology described by Brine. Brine, therefore, cannot reasonably be said to anticipate claim 1. Withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully requested.

Rejection of Claim 2 under 35 U.S.C. § 102(b)


Claim 2 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Domb (U.S. Patent No. 4,757,128 ). The Examiner relies upon his inherency argument set forth above to support his rejection of claim 2. Like Brine, Domb does not describe the terpolymers recited in claim 1, accordingly Domb can not be the same compositions recited in claim 1. Accordingly, the argument set forth above is also applicable to Domb and this reference can not be properly relied upon to support the subject rejection. Withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

Claims 1, 2, 4-7 are pending in the application. In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby requested.

In the event that there are any questions related to this response in particular, or to the application in general, the undersigned would appreciate the opportunity to address those questions directly in a telephone interview to expedite the prosecution of this application for all concerned.

Respectfully submitted



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